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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,605	09/27/2004	Tony Verbeuren	SERVIER 435 PCT	2292

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EXAMINER

JAVANMARD, SAHAR

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,605

Applicant(s)

VERBEUREN ET AL.

Examiner

SAHAR JAVANMARD

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/US)
Paper No(s)/Mail Date 09/27/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

This Office Action is in response to Applicant's Restriction Requirement remarks filed on March 28, 2008. Claim(s) 9-16 are pending. Claim(s) 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election of Group I, with traverse, drawn to a composition of compound A and aspirin of the restriction requirement in the reply is acknowledged.

Applicant submits that the technical feature of the claims is the composition of compound A and aspirin and its methods of use. The methods of claim 16 require the same technical feature as claims 9-16. However, in response, Examiner respectfully reiterates, "with respect to a group of inventions claimed in an international application unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description or drawings (if any)."(MPEP 1850 II. Determination of "Unity of Invention"). The special technical feature of Group I is a composition, containing compound A and aspirin while the special feature of Group II is a method of using said composition. The composition and

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the method of using the composition are different. Therefore, Applicant's arguments are not found persuasive.

The requirement is deemed proper and is therefore made FINAL. Claim(s) 9-15 are examined herein insofar as they read on the elected invention and species.

Objections

Claim 16 drawn to non-elected inventions has incorrect claim status identifier. Appropriate action is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavielle (US Patent No. 5,472,979) in view of Helgason (IEEE, 2000).

Lavielle teaches compounds of formula I, namely compound S 18886 and its sodium salt (see examples 1 and 7). Lavielle further teaches that these compounds are capable of inhibiting platelet aggregation (column 10, lines 43-45). The compounds may also be combined with one or more inert, non-toxic excipients or vehicles (column 10, lines 55-58).

Lavielle teaches a dosage regimen for S18886 ranging from 10-200 mg (column 11, lines 1-3).

Lavielle does not teach combining S18886 with aspirin. Further, Lavielle does not teach specifically the R optical isomer of S18886.

Helgason teaches a combination therapy consisting of aspirin and clopidogrel as a treatment regimen for the inhibition of platelet aggregation (page 215, column 1, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the platelet aggregate inhibitor, S18886, as taught by Lavielle and combined it with aspirin. The motivation, provided by Helgason, teaches a

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combination therapy regimen with aspirin and clopidogrel (both inhibitors of platelet aggregation) as a method of inhibiting platelet aggregation. Thus one would expect with a reasonable degree of success that combining S18886 with aspirin would also be effective because S1886 is also an inhibitor of platelet aggregation.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed S18886 as taught by Lavielle and used the R isomer. The expectation with regard to enantiomers is that activities as they pertain to living systems are expected to be different. *In re Adamson*, 275 F.2d 952, 125 PS.P.Q. 233 (C.C.P.A. 1960). The fundamentals of optical activity and stereoisomerism are well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have known how to resolve the racemic mixture and would have been motivated to do so with the reasonable expectation of achieving enantiomers having substantially different pharmacological activity. It appears as though applicant has determined experimentally what a person of ordinary skill in the art would have expected, namely, that the racemic mixture of the prior art may be separate (R) and (S) enantiomers possessing substantial different pharmacological activity. This is an expected result. It is well established that expected beneficial results are evidence of obviousness of a claimed invention just as unexpected beneficial results are evidence of unobviousness. *In re Skoll*, 523 F. 2d 1392, 187 U.S.P.Q. 481 (C.C.P.A. 1975); *In re Skoner*, 517 F. 2d 947, 186 U.S.P.Q. 80 (C.C.P.A. 1975); *In re Gershon*, 372 F. 2d 535, 152 U.S.P.Q. 602 (C.C.P.A. 1967);

A pure optical isomer is not patentable over the racemic mixture unless it possesses properties not possessed by the racemic mixture. *In re Anthony*, 414 F.2d 1383, 162 U.S.P.Q. 594 (C.C.P.A. 1969).

Conclusion

Claims 9-15 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617